

Atty. Dkt. No. 074022-3302

REMARKS

A detailed listing of all claims that remain under examination in the application is presented with the appropriate defined status identifier. Claims 1-12, 18, 19, 23, 25-34 and 36-62 are currently pending in the instant application. No claim has been amended by the present communication.

Rejection of claims 1, 23 and 36 under 35 U.S.C. § 102(e)(2) over Winkler.

The rejection of claims 1, 23 and 36 under 35 U.S.C. § 102(e)(2) as allegedly being anticipated by Winkler et. al., (US Pat No 6,849,462) is respectfully traversed.

In order to anticipate a claim, a single prior art reference must provide each and every element set forth in the claim. *In re Bond*, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990). See also, MPEP §2131. The Examiner bears the initial burden of establishing a *prima facie* case of anticipation. Only once that *prima facie* case has been established does the burden shift to the applicant to rebut the *prima facie* case. See, e.g., *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

The instant claims recite an assay device that includes the following elements:

- a) a support containing channels or a porous support;
- b) an optically functional layer that also contains channels;
- c) the optically functional layer having an optical property of which is detectably altered upon a change in mass resulting from analyte binding;
- d) the optically functional layer being positioned on the support; and
- e) the channels in the optically functional layer are positioned to allow fluid flow from the surface where analyte binding occurs to the support.

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The Winkler et al. patent is directed to methods and devices for generating high density arrays and for synthesizing different polymeric materials at specific locations on a substrate. See e.g., column 2, line 27-36. The reference discloses assay devices which have a series of horizontal "channels" formed across the surface of a substrate through which reagents can flow in order to synthesize polymers on the substrate surface. The Examiner points to Winkler et al., and alleges that devices disclosed therein anticipate the instant claims.

Applicant respectfully submits that the Examiner has failed to establish a *prima facie* anticipation rejection because the Examiner has failed to particularly identify each element of the instantly claimed device in the Winkler et al. disclosure. For example the Examiner has failed to point to any device in Winkler et al., that has channels both in a support and also in a functional layer as the instant claims require. If the "substrate" with channels of the Winkler devices allegedly represents the support containing channels as recited in the claims, then the Winkler et al. reference fails to disclose a functional layer that also contains channels. Conversely, if the "substrate", with channels of the Winkler et al. device allegedly represents a functional layer with channels as recited in the claims, then the Winkler et al. reference fails to disclose a support that also contains channels. Therefore, because the Winkler et al. devices do not have channels in both a functional layer and a support, the devices do not anticipate the instant claims.

Moreover, since the Winkler et al. devices do not have channels in a support and an optically functional layer, the devices cannot meet the claim elements requiring that the channels be positioned in an optically functional layer such as to allow fluid to flow to the support.

Accordingly, because the Winkler et al., reference fails to describe all of the elements of the claimed device, it cannot anticipate the claims. Reconsideration and withdrawal of the rejection is respectfully urged.

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Rejection of claims 1-7, 9, 18, 23, 25, 26, 36, and 51-54 under 35 U.S.C. §§ 102 (b) and (e)(2) over Miller et al.

The rejection of claims 1-7, 9, 18, 23, 25, 26, 36, and 51-54 under 35 U.S.C. §§ 102 (b) and (e)(2) as allegedly being anticipated by Miller et al., (U.S. Pat. No. 5,418,136) is respectfully traversed.

Specifically, it is asserted that Miller describes a "multi-pedestal device" wherein the "pedestals of the multi-pedestal device of column 39, lines 1-8, thus, support segments of an optically functional layer in such a device with either channels between the pedestals or pores in the support." Office Action, 5/31/05 p.3-4. Notably, this passage in the reference constitutes the entire basis on which the Examiner is attempting to show the existence of channels in the prior art device.

Although the Examiner states that there are channels between the pedestals, Miller et al., makes no reference whatsoever to "channels" in its assay device. The Examiner asserts that liquid can flow via space between pedestals and suggests that such spacing constitutes channels. Although space between pedestals may be implicit in the description by Miller et al., the existence of channels as an inherent features is not. Where a prior art reference does not expressly set forth a particular element of a claim, the reference can only anticipate the claim if the element is "inherent" in its disclosure. See MPEP §2131. To establish inherency, extrinsic evidence may be considered but the extrinsic evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 U.S.P.Q.2D (BNA) 1746, 1749 (Fed. Cir. 1991). "Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *Id.*, at 1269, 20 U.S.P.Q.2D (BNA) at 1749 (quoting *In re Oelrich*, 666 F.2d 578, 581, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981).

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According to the rejection, spacing between different pedestals of the multi-test device allegedly equates to channels in the claimed test device. However, the reference simply states that there are multiple pedestals upon each of which is a test surface. There is no mention in the reference regarding the distance, size, character of any such spacing that could possibly function as a channel and the Examiner has not cited to any such information.

Furthermore, in order to establish a *prima facie* anticipation rejection over the Miller et al., the Examiner must show that any spacing between pedestals necessarily has the character of a channel. *Id.* at 1269, 20 U.S.P.Q.2D (BNA) at 1749 (The mere fact that a certain thing may result from a given set of circumstances is not sufficient [for inherency]."). Thus, the mere assertion by the Examiner that space between things represents a channel does not satisfy a *prima facie* inherency rejection. Furthermore, Applicants respectfully submit that one of ordinary skill would not recognize spaces between pedestals as channels within the test surfaces of the assay device. In any event, the Examiner has failed to establish a *prima facie* rejection by inherency.

However, even if a *prima facie* inherency rejection had been established, (which it has not), the rejection fails on other grounds. Implicit and necessary for this rejection is that "segments of an optically functional layer" as described by the Examiner means that the segments together represent a single optically functional layer. However, the Examiner has cited to no teaching in Miller et al. that would support this possibility. Applicant respectfully submits that each test surface of the plurality of test surfaces in Miller et al. do not individually have channels. Furthermore, nothing in Miller et al. describes that the individual test surfaces are to be linked together in any manner that would represent a single optically functional layer. In fact, Miller et al. teaches a "multi-test device" with multiple pedestals where each test surface is distinct and independent. See, e.g., column 38 lines 35-41 ("a number of test surfaces, each uniformly coated with a different receptive material").

Accordingly, because the Miller et al., reference fails to describe all of the elements of the claimed device, either explicitly or inherently, it cannot anticipate the claims. Reconsideration and withdrawal of the rejection is respectfully urged.

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Rejection of claims 1-7, 9, 18, 23, 25, 26, 36, and 51-54 under 35 U.S.C. § 102 (f) over Miller et al.

The rejection of claims 1-7, 9, 18, 23, 25, 26, 36, and 51-54 under 35 U.S.C. § 102 (f) as allegedly being anticipated by Miller et al., (U.S. Pat. No. 5,418,136) is respectfully traversed. The rejection is without basis because the claims are patentable over Millar et al., as described above in the response to the rejection under 35 U.S.C. §§ 102 (b) and (e)(2).

Accordingly, because the instantly claimed invention is patentably distinct over the Miller et al. disclosure, it cannot anticipate the claims. Reconsideration and withdrawal of the rejection is respectfully urged.

Objection to Claim 11

Applicant respectfully disagree with the Examiner's assertion that claim 11 appears to be missing the word "on" in line 4. The claim should be understood to refer to a layer of germanium on which is placed a layer of diamond-like carbon. As such, the word "on" is present in the claim and located in the proper place. Reconsideration and withdrawal of the objection is respectfully urged.

Conclusion

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if there are any remaining issues in the case.

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The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-0872.

Respectfully submitted,

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